

**Application No. 09/785,831**  
**Amdt. dated February 23, 2004**  
**Reply to Office Action of October 23, 2003**

**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of the claims in the application.

**Listing of the Claims:**

Claims 1-124 (canceled)

Claim 125 (new)      A process for the manufacture of a prefilled syringe type ampoule having a) a barrel with a front end and a rear end defining an axis therebetween, the barrel having substantially constant cross-section between the front end and the rear end, at least the front end ending in an opening, b) a sealer attached to the front end and sealing the front end opening, c) at least one piston movably and sealingly arranged within the barrel and d) a sleeve extending along at least a part of the barrel, the sleeve having a front part and rear part, the front part being connected to the sealer, wherein the process comprises the steps of:

inserting the piston through the front end opening to a distance from the front end opening into a sealing engagement with the barrel interior to form a chamber between the piston and the front end opening;

filling material into the chamber by passing the material through the front end opening;

sealing the front end opening with the sealer; and

connecting the front part of the sleeve to the sealer after the step of sealing the front end opening with the sealer.

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Claim 126 (new)      The process of claim 125, wherein a lyophilizing step is performed before the step of sealing the front end opening with the sealer.

Claim 127 (new)      The process of claim 126, wherein the step of sealing the front end opening with the sealer includes the step of inserting a sealer part into the front end opening and contacting the sealer part with an interior surface of the barrel adjacent the front end opening.

Claim 128 (new)      The process of claim 126, further comprising the step of securing the sleeve to the barrel rear end.

Claim 129 (new)      The process of claim 126, wherein the step of sealing the front end opening with the sealer is performed in a sterilization zone and wherein the step of connecting the front part of the sleeve to the sealer is performed outside the sterilization zone.

Claim 130 (new)      The process of claim 129, further comprising the step of inserting a second piston through a rear opening at the rear end of the barrel, wherein the step of inserting the second piston is performed in the sterilization zone prior to the step of connecting the front part of the sleeve to the sealer outside the sterilization zone.

Claim 131 (new)      The process of claim 130, further comprising the step of performing a filling operation through the rear opening in the sterilization zone before inserting the second piston.

Claim 132 (new)      The process of claim 126, further comprising the step of inserting a second piston through a rear opening at the rear end of the barrel.

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Claim 133 (new)      The process of claim 132, further comprising the step of performing a filling operation through the rear opening before inserting the second piston.

Claim 134 (new)      The process of claim 125, wherein the step of sealing the front end opening with the sealer includes the step of inserting a sealer part into the front end opening and contacting the sealer part with an interior surface of the barrel adjacent the front end opening.

Claim 135 (new)      The process of claim 125, further comprising the step of securing the sleeve to the barrel rear end.

Claim 136 (new)      The process of claim 125, further comprising the step of inserting a second piston through a rear opening at the rear end of the barrel.

Claim 137 (new)      The process of claim 136, further comprising the step of performing a filling operation through the rear opening before inserting the second piston.

Claim 138 (new)      The process of claim 125, wherein the step of sealing the front end opening with the sealer is performed in a sterilization zone and wherein the step of connecting the front part of the sleeve to the sealer is performed outside the sterilization zone.

Claim 139 (new)      The process of claim 138, further comprising the step of inserting a second piston through a rear opening at the rear end of the barrel, wherein the step of inserting the second piston is performed in the sterilization zone prior to the step of connecting the front part of the sleeve to the sealer outside the sterilization zone.

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Claim 140 (new)      The process of claim 139, further comprising the step of performing a filling operation through the rear opening in the sterilization zone before inserting the second piston.

Claim 141 (new)      The process of claim 125, further comprising the step of inserting a second piston through a rear opening at the rear end of the barrel, wherein the step of inserting the second piston is performed in a sterilization zone and prior to the step of connecting the front part of the sleeve to the sealer.

Claim 142 (new)      The process of claim 141, further comprising the step of performing a filling operation through the rear opening in the sterilization zone before inserting the second piston.

Claim 143 (new)      A process for the manufacture of a prefilled syringe type ampoule having a) a barrel with a front end and a rear end defining an axis therebetween, the barrel having substantially constant cross-section between the front end and the rear end, at least the front end ending in an opening, b) a sealer attached to the front end and sealing the front end opening, c) at least one piston movably and sealingly arranged within the barrel and d) a sleeve extending along at least a part of the barrel, the sleeve having a front part and rear part, the front part being connected to the sealer, wherein the process comprises the steps of:

inserting the piston through the front end opening to a distance from the front end opening into a sealing engagement with the barrel interior to form a chamber between the piston and the front end opening;

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filling material into the chamber by passing the material through the front end opening;

sealing the front end opening with the sealer in a sterilization zone; and

connecting the front part of the sleeve to the sealer outside the sterilization zone.

Claim 144 (new)      The process of claim 143, wherein a lyophilizing step is performed before the step of sealing the front end opening with the sealer.

Claim 145 (new)      The process of claim 144, wherein the step of sealing the front end opening with the sealer includes the step of inserting a sealer part into the front end opening and contacting the sealer part with an interior surface of the barrel adjacent the front end opening.

Claim 146 (new)      The process of claim 144, further comprising the step of securing the sleeve to the barrel rear end.

Claim 147 (new)      The process of claim 144, further comprising the step of inserting a second piston through a rear opening at the rear end of the barrel.

Claim 148 (new)      The process of claim 147, further comprising the step of performing a filling operation through the rear opening before inserting the second piston.

Claim 149 (new)      The process of claim 144, further comprising the step of inserting a second piston through a rear opening at the rear end of the barrel, wherein the step

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of inserting the second piston is performed in the sterilization zone prior to the step of connecting the front part of the sleeve to the sealer outside the sterilization zone.

Claim 150 (new) The process of claim 149, further comprising the step of performing a filling operation through the rear opening in the sterilization zone before inserting the second piston.

Claim 151 (new) The process of claim 143, wherein the step of sealing the front end opening with the sealer includes the step of inserting a sealer part into the front end opening and contacting the sealer part with an interior surface of the barrel adjacent the front end opening.

Claim 152 (new) The process of claim 143, further comprising the step of securing the sleeve to the barrel rear end.

Claim 153 (new) The process of claim 143, further comprising the step of inserting a second piston through a rear opening at the rear end of the barrel.

Claim 154 (new) The process of claim 153, further comprising the step of performing a filling operation through the rear opening before inserting the second piston.

Claim 155 (new) The process of claim 143, further comprising the step of inserting a second piston through a rear opening at the rear end of the barrel, wherein the step of inserting the second piston is performed in the sterilization zone prior to the step of connecting the front part of the sleeve to the sealer outside the sterilization zone.

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Claim 156 (new)      The process of claim 155, further comprising the step of performing a filling operation through the rear opening in the sterilization zone before inserting the second piston.

Claim 157 (new)      A process for the manufacture of a prefilled syringe type ampoule having a) a barrel with a front end and a rear end defining an axis therebetween, the barrel having substantially constant cross-section between the front end and the rear end, at least the front end ending in an opening, b) a sealer attached to the front end and sealing the front end opening, c) at least one piston movably and sealingly arranged within the barrel and d) a sleeve extending along at least a part of the barrel, the sleeve having a front part and rear part, the front part being connected to the sealer, wherein the process comprises the steps of:

inserting the piston through the front end opening to a distance from the front end opening into a sealing engagement with the barrel interior to form a chamber between the piston and the front end opening;

filling material into the chamber by passing the material through the front end opening;

sealing the front end opening with the sealer;

inserting a second piston through a rear opening at the rear end of the barrel; and

connecting the front part of the sleeve to the sealer, wherein the step of inserting the second piston is performed prior to the step of connecting the front part of the sleeve to the sealer.

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Claim 158 (new)      The process of claim 157, wherein a lyophilizing step is performed before the step of sealing the front end opening with the sealer.

Claim 159 (new)      The process of claim 158, wherein the step of sealing the front end opening with the sealer includes the step of inserting a sealer part into the front end opening and contacting the sealer part with an interior surface of the barrel adjacent the front end opening.

Claim 160 (new)      The process of claim 158, wherein the step of connecting the front part of the sleeve to the sealer is performed after the step of sealing the front end opening with the sealer.

Claim 161 (new)      The process of claim 160, further comprising the step of securing the sleeve to the barrel rear end.

Claim 162 (new)      The process of claim 160, further comprising the step of performing a filling operation through the rear opening in a sterilization zone before inserting the second piston.

Claim 163 (new)      The process of claim 158, further comprising the step of performing a filling operation through the rear opening before inserting the second piston.

Claim 164 (new)      The process of claim 157, wherein the step of sealing the front end opening with the sealer includes the step of inserting a sealer part into the front end opening and contacting the sealer part with an interior surface of the barrel adjacent the front end opening.



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Claim 165 (new)      The process of claim 157, further comprising the step of securing the sleeve to the barrel rear end.

Claim 166 (new)      The process of claim 157, further comprising a step of performing a filling operation through the rear opening in the sterilization zone before inserting the second piston.

Claim 167 (new)      The process of claim 157, wherein the step of inserting the second piston is performed in a sterilization zone.